K011740

CONFIDENTIAL DOCUMENT

MedDev
CORPORATION

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JUL - 2 2001

SPECIAL 510(K) SUMMARY

In accordance with CFR 807.92 the following information is submitted:

1. Submitter: MedDev Corporation
   730 North Pastoria Avenue
   Tel.: (408) 730-9702
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   Contact: Suzanne Brick, Operations Administrator

   Registration Number: 2921577

   Date of Summary: Monday, June 18, 2001

2. Device Name: Contour™ Design Gold Eyelid Implants

   Common Name: Gold Eyelid Weight

   Classification: Class II; Eyelid Weights, External

3. Predicated Devices: MedDev Contour™ Design Gold Eyelid Implants, preamendment devices
   Labtician Lid Load™ Gold Eyelid Weight Implants, 510(k) number K983607

4. Description of Modified Device:
   MedDev's Contour Design Gold Eyelid Implants are spherically radiused parts of gold (at least 99.99% pure) which conform to the curvature of the eye globe. They are available in twelve sizes ranging from 0.6 grams to 2.8 grams in 0.2-gram increments. All product specifications are the same or substantially equivalent to the predicated devices mentioned above. The sole difference between the predicated MedDev devices and the proposed Contour Design Gold Eyelid Implants is that the devices will now be supplied sterile to end users.

   MedDev's Contour Design Gold Eyelid Implants can be implanted into the eyelid using the surgical techniques depicted in the product brochure. This technique is the same or substantially equivalent to techniques used for the predicated devices.

5. Indications for Use:
   The Indications for Use of the proposed Contour Design Gold Eyelid Implants is **exactly** the same as for the original Contour Design Gold Eyelid Implants. The broad indication for prescribing MedDev's Contour Design Gold Eyelid Implants is for the gravity-assisted treatment of protracted or permanent lagophthalmos, usually resulting from facial paralysis.

Conditions, which may damage the facial nerve, include Bell's palsy, facial nerve injury, trauma, tumor invasion, and resection of tumors, i.e. acoustic neuroma and parotidectomy.

6. Technical Specifications for the Device:
MedDev's Contour Design Gold Eyelid Implants are made of 99.99% pure gold. They are designed in a rectangular shape with a spherical radius of 12.7 mm to conform to the shape of the globe. The implant has rounded corners and tapered, smooth edges. Suture holes are placed in the implant, allowing the surgeon to secure the implant to the tarsus or orbital septum.

7. Comparison and Substantial Equivalence:
With the exception of sterility, all technological characteristics of the proposed Contour Design Gold Eyelid Implants, the current Contour Design Gold Eyelid Implants and Labtician Lid Load Gold Eyelid Weight Implants are the same or substantially equivalent. The proposed Contour Design Gold Eyelid Implants are the same implants as the predicated Contour Design Gold Eyelid Implants, but now will be sold sterile. The proposed MedDev Contour Design Gold Eyelid Implants will be sterilized by steam using a validated sterilization cycle providing a Sterility Assurance Level of 1×10^{-6}.

SUBSTANTIAL EQUIVALENCE COMPARISON

	Proposed MedDev Contour Design Gold Eyelid Implant	MedDev Contour Design Gold Eyelid Implants	Labtician Lid Load Gold Eyelid Weight Implants
Indications for Use	Same	Same	Same
Target Population	Same	Same	Same
Design	Same	Same	Same
Materials	Same	Same	Same
Performance	Same	Same	Same
Sterility	Sterile	Non-Sterile	Sterile
Biocompatibility	Same	Same	Same
Mechanical Safety	Same	Same	Same
Anatomical Site	Same	Same	Same
Human Factors	Same	Same	Same
Where Used	Same	Same	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL - 2 2001

Suzanne Brick
Operations Administrator
MedDev Corporation
730 North Pastoria Avenue
Sunnyvale, CA 94085-

Re: K011740
Contour™ Design Gold Eyelid Implants
Unclassified
Product Code: MML
Dated: May 31, 2001
Received: June 5, 2001
Amended: June 22, 2001

Dear Ms. Brick:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear, Nose and
Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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INDICATIONS FOR USE STATEMENT

1. 510(k) Number: Preamendment Device

2. Device Name: MedDev Contour Design Gold Eyelid Implants

3. Indications for Use:
The MedDev Contour Design Gold Eyelid Implants intended use is for the gravity-assisted treatment of protracted or permanent lagophthalmos, usually resulting from facial paralysis.

The intended use and indications for use of the proposed device have not changed at all.

PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use___X___ OR Over-The-Counter Use_____
(Per 21 CFR 801. 109)

Joel P. [illegible]
(Division Sign-Off)
Division of Ophthalmic Devices
510(k) Number 011740